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November 9, 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

NOV 15 2005

To the Food and Drug Administration

Pursuant to section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act (FDA Act), 21 USA 343, we hereby notify the FDA that Futurebiotics LLC has included the following statement in labeling for the dietary supplement that it manufactures and markets. The following information is provided:

Manufacturer: Futurebiotics LLC
70 Commerce Drive
Hauppauge, NY 11788


Statement text: Clinically proven nutrients for hot flashes + night sweats

Dietary ingredient: Black Cohosh extract

Dietary Supplement: Futurebiotics EstroComfort™

I certify that the information contained in this notice is complete and accurate and that Futurebiotics LLC has substantiation that the statement is truthful and not misleading.

Sincerely



Steve Welling
Chief Operating Officer

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